Docket No. DEP-5170USNP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Michael Slivka et al.	Confirmation No. 7650
Serial No.	:	10/676,868	Art Unit: 1651
Filed	:	September 30, 2003	Examiner: L.B. Lankford, Jr.
For	:	METHODS FOR TREATMENT OF DEFECTS IN THE INTERVERTEBRAL DISC	

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January 28, 2008	Theodore J. Shatynski
Date of Transmission and Signature	**Name of Applicant, Assignee, or Registered Representative**

/Theodore J. Shatynski/

Signature

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Commissioner for Patents
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ATTENTION: BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANT'S BRIEF (37 C.F.R. 1.192)

Dear Sir:

This is an appeal from the Final Rejection mailed August 24, 2007, a Notice of Appeal having been received by the USPTO on November 26, 2007. Appellant's Brief is being submitted January 28, 2008 noting that January 26, 2008 fell on a Saturday.

The Commissioner is hereby authorized to charge the fees required under 1.171(f) for any additional fees which may be required, or credit any overpayment to Account No. 10-0750/DEP-5170USNP/TJS.

This brief contains these items under the following headings, and in the order set forth below (37 CFR 1.192(c)):

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1. REAL PARTY INTEREST

The real party in interest of the subject patent application is DePuy Spine, Inc. having a principal place of business at 325 Paramount Drive, Raynham, MA 02767.

2. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences pending.

3. STATUS OF CLAIMS

3.1 Claims 1, 4-12 and 14-41 stand rejected under 35 U.S.C. §112 as failing to comply with the enablement requirement.

4. STATUS OF AMENDMENTS

No amendment after Final Rejection has been filed.

5. SUMMARY OF CLAIMED SUBJECT MATTER

One embodiment of this invention relates to a method of treating spinal disc defects comprising the steps of:

a) preparing a disc treatment site;

b) providing a substantially two-dimensionally shaped disc defect repair material in the form of a strip; and

c) inserting the repair material into the disc to be repaired. (Spec. page 4, lines 5-10 and claim 1).

Another embodiment of this invention relates to a method of treating spinal disc defects comprising the steps of:

a) preparing a disc treatment site;

b) manipulating a substantially two-dimensionally shaped disc defect repair material into a mushroom shape; and

c) inserting the repair material into the disc to be repaired. (Spec. page 4, lines 12-17 and claim 41).

Further embodiments of this invention include providing and using the disc defect repair materials that have been seeded with cells and /or treated with bioactive factors. (Spec. page 4, lines 19-21).

Advantages of the invention include the fact that it provides a minimally invasive approach to disc repair particularly in maintaining disc height, resisting nucleus leakage and in preferred embodiments promoting regeneration of the native disc structure. The invention has an additional benefit in that the invention permits nucleus pulposus augmentation and annular ring plugging in a single procedure. (Spec. page 4, lines 23-28).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

6.1 Claims 1, 4-12 and 14-41 are unpatentable under 35 U.S.C. §112 as not being enabled.

7. ARGUMENTS

7.1 Claims 1, 4-12 and 14-41 are enabled.

The gist of the Examiner's argument is that::

> ". . .the disclosure of the instant specification is too limited to be considered enabling for treatment of any spinal disc defect with the generically claimed materials, particularly wherein the claimed repair materials encompass any and all bioabsorbable materials." (Final Rejection, page 2, lines 19-22).

> "To be able to practice the claimed invention at the claimed scope would require undue experimentation to determine what materials would actually work to effectively treat a spinal disc disorder." (Final Rejection, page 3, lines 4-6).

> "The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented

> in the instant specification and the prior art of record." (Final Rejection, page 3, lines 22-25).
>
> "In the instant case, for the reasons set forth above, the broad scope of the instant claims do not bear a reasonable correlation to the scope of enablement provided by the specification; and thus the claims are not deemed enabled for their full scope." (Final Rejection, page 4, lines 21-23).

However, clearly the Examiner's position ignores the wide variety of materials already disclosed and known to those skilled in the art suitable for use in intervertebral disc repair. Appellant reproduces portions of the Background of the Invention which describes some of the suitable materials for use in intervertebral discs repair already know to those of skill in the art:

> "Lambrecht et. al (PCT/WO0112107A1) disclose a barrier prosthesis such as a plug made of biocompatible material with anchoring means for repairing the annulus and supporting the nucleus pulposus. Disclosed materials include flexible, biocompatible materials, fibrous materials such as collagen or cellulose, and hydrogels. Also disclosed are porous materials that provide tissue ingrowth and bioabsorbable materials, although these are not presented as preferred embodiments." (Spec. page 2, lines 1-7).
>
> "Ferree (PCT/WO0110316, US6245107) discloses treatment of annular defects using a material which is inserted into the disc in a first insertable state and then is allowed to expand, return or solidify into a second state which occludes the defect. Bioabsorbable materials are mentioned but no disclosure is made regarding materials that are tissue conductive, and no mention is

> made of SIS. Further, no method is provided whereby a 2-D structure is twisted or packed into the disc structure." (Spec. page 2, lines 9-15).
>
> "Haldimann (PCT/WO0062832) discloses an in-situ curable polymeric adhesive that is used to fill the disc defect and adhere to the adjacent tissues. Guagliano and Ross (US6,206,921 B1) disclose a similar system to Haldimann where an injectable, setting, resilient material is used to replace the nucleus pulposus. Stovall (PCT/WO9904720) discloses using a cell containing hydrogel to treat herniated discs. Bao and Yuan (PCT/WO9961084) disclose an expandable, porous material to seal biological apertures and permit tissue ingrowth. Felt et al. (US6,140,452) disclose an injectable, curable polyurethane to repair tissue sites. Sharkey et al. (US6,126,682) disclose a method of heating the annulus to weld the defect that can be coupled with a delivery of sealing agents. Gan et al. (US5964807) disclose porous hybrid materials containing sol gel bioactive material that can be used to repair the disc. Plouhar et al. (US5922028) disclose a tissue graft consisting of secured layers of intestinal submucosa which is sculptured to have the anatomical shape of the cartilaginous structure that is to be repaired." (Spec. page 2, line 17 to page 3, line 4).

However, the prior art does not disclose any methods whereby a substantially two-dimensionally shaped structure is twisted or packed into the disc structure as described and claimed by Appellant.

Clearly, the foregoing examples are not a complete list of all suitable materials known or that may become known to those of skill in the art suitable for use in the repair of intervertebral discs. Appellant's invention is the insertion of a substantially two-

dimensionally shaped structure in the form of a strip that is twisted or packed into an intervertebral disc. Thus one skilled in the art is enabled to use a suitable intervertebral disc material in the form of a strip to repair an intervertebral disc.

Furthermore, the Examiner's rejection is clearly overly broad as it appears to ignore the further dependent claims that provide specific examples of suitable materials, many of which have been described in the above foregoing discussion from the Background of the Invention and in the specification.

8. CONCLUSION

For the foregoing reasons, the reversal of the rejection relating to claims 1, 4-12 and 14-41 are respectfully requested.

9. APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

(See attached)

10. EVIDENCE APPENDIX

None

11. RELATED PROCEEDINGS APPENDIX

None

Respectfully submitted,

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APPENDIX OF CLAIMS INVOLVED IN THE APPEAL

1. (Previously amended) A method of treating spinal disc defects comprising the steps of:
   a) preparing a disc treatment site;
   b) providing a substantially two-dimensionally shaped disc defect repair material in the form of a strip; and
   c) inserting the repair material into the disc to be repaired.

2-3. (Canceled)

4. (Original) The method of claim 1, wherein the disc repair material comprises a porous, biocompatible material.

5. (Original) The method of claim 4, wherein the bioabsorbable or non bioabsorbable material.

6. (Original) The method of claim 5, wherein the material is a bioabsorbable material selected form the group consisting of small intestine submucosa (SIS), collagen, hyaluronic acid, elastin, albumin, reticulin, synthetic polyamino acids, prolamines, polysaccharides, alginate, heparin, biodegradable polymers of sugar units, synthetic polymers including polylactide, polyglycolide, polydioxanone, polyhydroxybutyrate, polyhydroxyvalerate, poly(propylene fumarate), polyoxaesters, synthetic polyamino acids, biodegradable polyurethanes and their copolymers, and combinations thereof.

7. (Original) The method of claim 6, wherein the bioabsorbable material is SIS.

8. (Withdrawn) The method of claim 6, wherein the bioabsorbable material is collagen.

9. (Withdrawn) The method of claim 5, wherein the material is a non-bioabsorbable material.

10. (Withdrawn) The method of claim 9, wherein, the non-bioabsorbable material is selected from the group consisting of polyacrylates, ethylene-vinyl acetates (and other acyl-substituted cellulose acetates), polyester (Dacron®), poly(ethylene terephthalate), polypropylene,

polyethylene, polyurethanes, polystyrenes, polyvinyl oxides, polyvinyl fluorides, poly(vinyl imidazoles), chlorosulphonated polyolefins, polyethylene oxides, polyvinyl alcohols (PVA), polytetrafluoroethylenes, nylons, and combinations thereof.

11. (Withdrawn) The method of claim 10, wherein the non-bioabsorbable material is polyester (Dacron®).

12. (Original) The method of claim 1, wherein the step of inserting further comprises twisting the material being inserting into the disc.

13. (Canceled)

14. (Presently amended) The method of claim 12, wherein the material is selected form the group consisting of SIS, collagen, hyaluronic acid, elastin, albumin, reticulin, synthetic polyamino acids, prolamines, polysaccharides, alginate, heparin, biodegradable polymers of sugar units, synthetic polymers including polylactide, polyglycolide, polydioxanone, polyhydroxybutyrate, polyhydroxyvalerate, poly(propylene fumarate), polyoxaesters, synthetic polyamino acids, biodegradable polyurethanes and their copolymers, and combinations thereof.

15. (Withdrawn) The method of claim 14, wherein the material is collagen.

16. (Original) The method of claim 14, wherein the material is SIS.

17. (Previously amended) The method of claims 1, 4-7, 12-14, and 16, wherein the material is cell seeded.

18. (Original) The method of claim 17, wherein the cells are selected from stem cells, bone marrow cells, fibrocytes, adipocytes, chondrocytes, cells harvested from spinal discs in the body such as nucleus pulposus cells and annulus fibrosis, and combinations thereof.

19. (Withdrawn) The method of claim 18, wherein the cells are stem cells.

20. (Withdrawn) The method of claims 1-16, wherein the material is combined with an autologous medium prior to implantation.

21. (Previously amended) The method of claims 1, 4-7, 12-14, and 16, wherein the material is combined with an autologous medium is selected from platelet-rich plasma, platelet-poor plasma, bone marrow, whole blood and serum.

22. (Original) The method of claim 20, wherein the autologous medium is bone marrow.

23. (Original) The method of claim 1-16 wherein the material further comprises a bioactive factor.

24. (Original) The method of claim 23 wherein, the bioactive agent is selected from the group consisting of transforming growth factor-beta and agents in the same family of growth factors, platelet-derived growth factors, fibroblast growth factors, insulin-like growth factors, protein polymers such as RGD-peptides and Indian Hedgehog proteins, anti-inflammatory agents, angiogenic factors, hormones, hyaluronic acid and combinations thereof.

25. (Original) The method of claim 24, wherein the bioactive factor is a transforming growth factor-beta selected from the group consisting of TGF-ßl, TGF- ß2, and TGF-ß3, GDF-5, MP52, and BMPs .

26. (Original) The method of claim 17 wherein the material further comprises a bioactive factor.

27. (Original) The method of claim 26 wherein the bioactive factor is selective form the group consisting of transforming growth factor-beta and agents in the same family of growth factors, platelet-derived growth factors, fibroblast growth factors, insulin-like growth factors, protein

polymers such as RGD-peptides and Indian Hedgehog proteins, anti-inflammatory agents, angiogenic factors, hormones, hyaluronic acid and combinations thereof.

28. (Original) The method of claim 27 wherein the bioactive factor is a transforming growth factor-beta selected from the group consisting of TGF-ßl, TGF- ß2, and TGF-ß3, GDF-5, MP52, and BMPs .

29. (Original) The method of claim 18 wherein the material further comprises a bioactive factor.

30. (Original) The method of claim 29 wherein the bioactive factor is selective form the group consisting of transforming growth factor-beta and agents in the same family of growth factors, platelet-derived growth factors, fibroblast growth factors, insulin-like growth factors, protein polymers such as RGD-peptides and Indian Hedgehog proteins, anti-inflammatory agents, angiogenic factors, hormones, hyaluronic acid and combinations thereof.

31. (Original) The method of claim 30 wherein the bioactive factor is a transforming growth factor-beta selected from the group consisting of TGF-ßl, TGF- ß2, and TGF-ß3, GDF-5, MP52, and BMPs .

32. (Original) The method of claim 20 wherein the material further comprises a bioactive factor.

33. (Original) The method of claim 32 wherein the bioactive factor is selective form the group consisting of transforming growth factor-beta and agents in the same family of growth factors, platelet-derived growth factors, fibroblast growth factors, insulin-like growth factors, protein polymers such as RGD-peptides and Indian Hedgehog proteins, anti-inflammatory agents, angiogenic factors, hormones, hyaluronic acid and combinations thereof.

34. (Original) The method of claim 33 wherein the bioactive factor is a transforming growth factor-beta selected from the group consisting of TGF-ßl, TGF- ß2, and TGF-ß3, GDF-5, MP52, and BMPs .

35. (Original) The method of claim 21 wherein the material further comprises a bioactive factor.

36. (Original) The method of claim 35 wherein the bioactive factor is selective form the group consisting of transforming growth factor-beta and agents in the same family of growth factors, platelet-derived growth factors, fibroblast growth factors, insulin-like growth factors, protein polymers such as RGD-peptides and Indian Hedgehog proteins, anti-inflammatory agents, angiogenic factors, hormones, hyaluronic acid and combinations thereof.

37. (Original) The method of claim 36 wherein the bioactive factor is a transforming growth factor-beta selected from the group consisting of TGF-ßl, TGF- ß2, and TGF-ß3, GDF-5, MP52, and BMPs .

38. (Original) The method of claim 22 wherein the material further comprises a bioactive factor.

39. (Original) The method of claim 38 wherein the bioactive factor is selective form the group consisting of transforming growth factor-beta and agents in the same family of growth factors, platelet-derived growth factors, fibroblast growth factors, insulin-like growth factors, protein polymers such as RGD-peptides and Indian Hedgehog proteins, anti-inflammatory agents, angiogenic factors, hormones, hyaluronic acid and combinations thereof.

40. (Original) The method of claim 39 wherein the bioactive factor is a transforming growth factor-beta selected from the group consisting of TGF-ßl, TGF- ß2, and TGF-ß3, GDF-5, MP52, and BMPs .

41. (Original) A method of treating spinal disc defects comprising the steps of:

a) preparing a disc treatment site;

b) manipulating a substantially two-dimensionally shaped disc defect repair material into a mushroom shape; and

c) inserting the repair material into the disc to be repaired.